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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/655,571 | 09/04/2003 | John A. Sazy | 3518.1016-000 | 6429 |

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| EXAMINER | |
|---|---|
| PELLEGRINO, BRIAN E | |
| ART UNIT | PAPER NUMBER |
| 3738 | |

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/655,571 | SAZY, JOHN A. | |
| | Examiner | Art Unit | |
| | Brian E. Pellegrino | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-6 and 10-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 10-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the written disclosure does not describe "edges that each form smoothly-sloping surfaces." Additionally, the written disclosure does not describe the body of the prosthesis with a "front arc having a first radius of curvature equal to a back arc having a second radius of curvature". The specification also failed to describe the "openings as quadrilaterals, or parallelograms or rhombuses."

### *Claim Rejections - 35 USC § 102*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6,10-14,28 are rejected under 35 U.S.C. 102(b) as being anticipated by Harms et al. (4820305). Fig. 1 shows an intervertebral implant formed as a unitary body with an exterior surface and interior surface defining a recess or cylinder.
Harms shows (Fig. 6) the body having a banana-shape and a first continuous radius of curvature less than a second continuous radius of curvature and extend from a single point of rotation. Harms also discloses that each V-shape edge forms a smoothly sloping surfaces since they are chamfered, col. 2, lines 26-30. It can be seen that the body has rhombus shaped openings (col. 2, lines 15,16) about the circumference and are evenly spaced. Harms additionally discloses the prosthesis

is made of metal, col. 4, line 9. Clearly, the interlinked mesh forms a "serpentine *arrangement.*"

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harms et al. '305 in view of Dove et al. '261. Harms et al. is explained supra. However, Harms et al. fail to disclose the material for the prosthesis is made from a carbon-fiber reinforced plastic or polymer or stainless steel. Dove et al. teach that the spinal implant can be made from a variety of materials, such as carbon fiber reinforced polymers or stainless steel or biodegradable material, col. 1, lines 46-51. It would have been obvious to one of ordinary skill in the art to use alternative materials as taught by Dove et al. for the implant of Harms et al. such that it can provide a lighter implant or a more radiopaque implant or one that degrades as tissue ingrowth occurs.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harms et al. '305 in view of Michelson (6302914). Harms et al. is explained above. However, Harms et al. fail to disclose the implant's height or width. Michelson (Fig. 18) shows a spinal cage for supporting the vertebrae. Michelson also teaches that the height and width of the implant correspond to the area that a disc may heave been removed, col. 7, lines 47-56. It would have been obvious to one of ordinary skill in the art to use an implant with a width falling within the range of 24-28mm and a height

falling within the range of 10-16mm and a length of about 10mm as taught by Michelson for the implant of Harms et al. such that it can provide the proper dimensions of the patients intervertebral space and support adjacent vertebrae.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harms et al. '305 in view of Dove et al. '261 as applied to claim 20 above, and further in view of MacMillan et al. (5062850). Harms et al. in view of Dove et al. is explained supra. However, Harms as modified by Dove fail to disclose the use of polyglycolic acid for the spinal support device. MacMillan et al. teach the use of polyglycolic acid for the vertebral prosthesis because it slowly degrades, col. 6, lines 5-10. . It would have been obvious to one of ordinary skill in the art to use polyglycolic acid as the implant material as taught by MacMillan et al. for the vertebral implant of Harms et al. as modified by Dove et al. such that it degrades slowly to provide space for bone ingrowth.

Claims 19,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harms et al. '305 in view of Biscup (6245108). Harms et al. is explained supra. However, Harms fails to disclose the use of a polymer such as polymethylmethacrylate for the spinal support device. Biscup teaches the use of polymers such as polymethylmethacrylate for the vertebral prosthesis because it is inert and biocompatible, col. 3, lines 60-66. It would have been obvious to one of ordinary skill in the art to use polymethylmethacrylate as the implant material as taught by Biscup for the vertebral implant of Harms et al. such that it is accepted by the patient's body and does not adversely cause irritation.

Claims 19,22,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harms et al. '305 in view of Preissman (6231615). Harms et al. is explained supra. Harms does disclose the use of bone cement, but does not explicitly disclose any particular type or use of agents with it. However, Harms fails to disclose the use of an antibiotic with the cement. Preissman teaches the use of injectable PMMA and the use of an antibiotic, col. 4,lines 2-10. Preissman also teaches the injectable PMMA is used in treating pain in vertebral compression fractures, col. 3, lines 65-67. It would have been obvious to one of ordinary skill in the art to inject polymethylmethacrylate with an antibiotic as taught by Preissman with the vertebral implant of Harms et al. such that it is enhances the treatment given to the patient to reduce infection and provides an efficient way to deliver a cement and antibiotic to the treatment site.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harms et al. '305 in view of Michelson (6302914) as applied to claim 26 above, and further in view of McKay (5702449). Harms et al. in view of Michelson is explained supra. However, Harms as modified by Michelson fail to disclose the thickness of front arc of the implant to be about 1.5-2mm. McKay teaches (Fig. 5) a spinal implant and that the thickness of a front arc can be "about 1mm". McKay also teaches (col. 6, lines 38-40, 53,54) the thickness is sufficient to support the vertebrae and not break. The Examiner is interpreting "about 1.5mm" to be "about 1mm". It would have been obvious to one of ordinary skill in the art to use a thickness for the arc of the implant of "about 1.5mm" as taught by McKay for the implant of Harms as modified by Michelson such that it provides a durable support for the vertebrae that can withstand compressible loads.

### *Response to Arguments*

Applicant's arguments filed 7/3/06 have been fully considered but they are not persuasive. The Applicant contends that the Harms' device is not unitary. However, it can be construed that the device is "unitary" because it is secured together to form a single "unitary" or functioning implant. Unitary can be defined as multiple things working together to form a "unit". It is also noted that Applicant failed to address some objections found for limitations not in the disclosure. The Examiner interprets Harms to disclose these as best understood as to what Applicant is attempting to claim since these objections were not addressed. Applicant also argues that the prior art does not disclose a "serpentine arrangement," but fails to describe what this means. Clearly, Harms illustrates an interlinked mesh just as disclosed and claimed by Applicant and it can be construed that since Harms' arrangement of the mesh is zig-zag it is a "serpentine arrangement".

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER